In the Supreme Court of the United States

OCTOBER TERM, 1964

No. 224

DETROIT VITAL FOODS, INC., PETITIONER

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals is reported at 330 F.2d 78. The opinion of the district court is reported at 192 F. Supp 51.

JURISDICTION

The judgment of the court of appeals was entered on March 31, 1964. The petition for a writ of certiorari was filed June 29, 1964. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

1. Whether misbranded tablets, made up within a State by combining several drugs which had moved in interstate commerce under proper labeling, are subject to seizure under Section 304(a) of the Federal Food Drug and Cosmetic Act as a drug misbranded while held for sale after shipment in interstate commerce.

2. Whether in permitting such seizure the Act transcends the constitutional powers of Congress.

STATUTES INVOLVED

Section 304(a) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 334(a)) provides in pertinent part:

> Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce or while held for sale (whether or not the first sale) after shipment in interstate commerce, * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found * * *.

STATEMENT

This is a seizure action *in rem* filed in the United States District Court for the Eastern District of Michigan against "Mich. Brand Korleen Tablets" alleged to have been misbranded while held for sale after shipment in interstate commerce. It is not dis-

puted that if the tablets are subject to seizure under the Federal Food, Drug and Cosmetic Act, they were properly found to have been misbranded with respect to their utility in the treatment of disease. The issue raised is whether the articles were "held for sale after shipment in interstate commerce" within the terms of the Act.

The tablets at issue were made up in Michigan by combining various drugs (choline, inositol, methionine, niacinamide, and thiamine) which had been shipped into Michigan from out of the State under labeling the validity of which is not questioned. The tablets were delivered in Michigan to petitioner, whose literature as to the curative effect of the tablets forms the basis of the misbranding charge.

The district court, in rejecting petitioner's argument that the federal act did not apply to the tablets since they were a new product made in Michigan, pointed out that one of the leaflets forming the basis for the libel "emphasizes the treatment of certain disorders through the utilization of choline" and that the leaflet then mentions that Korleen tablets contain large amounts of choline combined with the other drugs (Pet. App. 18). The court noted that "the 'drugs' comprising the Korleen Tablets are the very heart of the manufactured and tableted 'drug' and were proclaimed as such to the public." (Pet. App. 19). It ruled that the tablets were being held for sale after shipment in interstate commerce within the meaning of the Act, and that it "would be a strained interpretation to say that each 'drug' component falls

within the jurisdiction of the Act, being shipped in interstate commerce, but, when compounded together to form another 'drug', the finished product is not being held for sale after shipment in interstate commerce." (Pet. App. 18). The court of appeals affirmed, ruling that the combination of the various drugs into one tablet did not "form something new and different" (Pet. App. 27).

ARGUMENT

1. The foundation of petitioner's arguments, statutory and constitutional, is the claim that the tablets are a new product, as different from their individual components as a loaf of bread is different from flour, butter, eggs and yeast. This is a faulty premise. As both courts below pointed out, petitioner's own literature referred to the separate component drugs which made up the tablets in a way which showed that each did not lose its character as a drug. In effect, petitioner offered several different drugs in one dose. The tablets were thus merely a method of combining several drugs which had been shipped in interstate commerce and were properly seized as misbranded while "held for sale after shipment in interstate commerce." The statute defines "drug" to include components. See Section 301(g), 21 U.S.C. 321(g).

This case is, as the court below noted, similar to *United States* v. *40 Cases* * * * *Pinocchio Brand*, 289 F.2d 343, 346 (C.A. 2), certiorari denied, 368 U.S. 831, where several different vegetable oils were combined, packaged, and sold within one State under labelling which misrepresented the olive oil content.

In holding that the repackaged combinations of oils fell within the reach of the federal act, the court rejected the contention that "the blending of the oils which had been transported in interstate commerce took the final product out from under federal regulation although each of its separate components was being held for sale after shipment in interstate commerce" (289 F.2d at p. 345). See, also, *United States* v. *Allbrook Freezing and Cold Storage Inc.*, 194 F.2d 937, 939. (C.A. 5). Nothing in the words of the statute, or the facts of this case, requires the courts to permit easy evasion of federal requirements for protection of the consumer by the simple device of combining several drugs in one tablet and misbranding them. Petitioner recognizes that the legislative history of the "held for sale" clause and this Court's decision in *United States* v. *Sullivan*, 332 U.S. 689, indicate that, as to a product which has itself passed through interstate commerce, the act "unqualifiedly prohibits misbranding articles held for sale after shipment in interstate commerce, without regard to how long after the shipment the misbranding occurred, how many intrastate sales had intervened, or who had received the articles at the end of the interstate shipment" (332 U.S. at p. 696). Thus, the drug choline, if repackaged in Michigan and then sold with petitioner's literature, would unquestionably be subject to seizure under the federal Act in petitioner's retail store. The situation is not changed by the fact that the tablets combined that drug with others. There is no such "loophole." Cf. *Kordel* v. *United States*, 335

U.S. 345, 349; *United States* v. *Wiesenfeld Warehouse Co.*, 376 U.S. 86, 92.

2. The constitutionality of the statute as applied to a product misbranded while held for sale after shipment in interstate commerce was settled by the decision in *United States* v. *Sullivan*, 332 U.S. 689, where the Court recognized that the Act was designed to cover "every article that had gone through interstate commerce until it finally reached the ultimate consumer" and ruled that, so construed, the Act was not beyond the authority of Congress. 332 U.S. at pp. 697-698. Petitioner argues that the *Sullivan* decision does not extend to a "new product" manufactured and sold within one State. As discussed *supra*, this argument is unavailing to petitioner, for the tablets here involved were not really a new product; they represented a combination of drugs which had been shipped interstate and which were merely combined and repackaged within the State.

CONCLUSION

It is therefore respectfully submitted that the petition for a writ of certiorari should be denied.

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